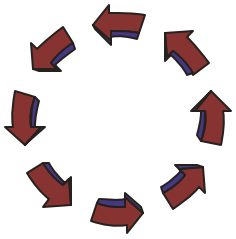
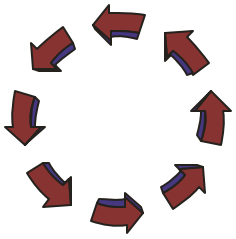
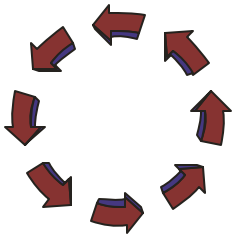


# Reprocessing of Single-Use Devices (SUDs) by Hospitals and Third-Parties



# Why is reuse of SUDs a concern?

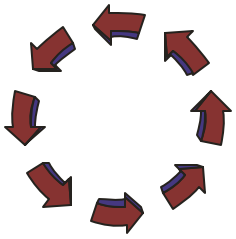
- The public is concerned.
- FDA research shows reuse may be feasible, but
  - difficult and
  - possibly dangerous.
- Minimal evidence of problems does not mean that reuse is safe and effective.



# Enforcement Priorities Guidance

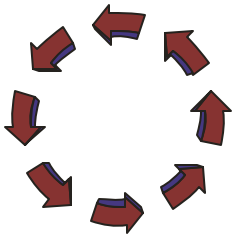
"Enforcement Priorities for Single-Use Devices Reprocessed
by Third Parties and Hospitals"

www.fda.gov/cdrh/comp/guidance/1168.pdf



# Scope of SUD Enforcement Guidance

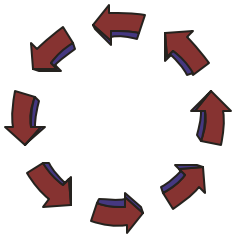
- Applies to third-party & hospital SUD reprocessors.
- Does not apply to:
  - permanently implantable pacemakers,
  - "open-but-unused" SUDs,
  - healthcare facilities that are not hospitals, and
  - hemodialyzers.



# Time Table for Enforcement
## (revised as of 8/14/01)

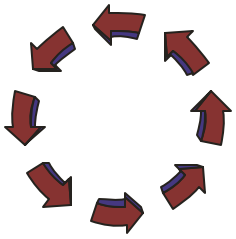
- Premarket Requirements
  - **February 14, 2001**, for all class III devices*
  - **August 14, 2001**, for class II non-exempt devices
  - **February 14, 2002**, for class I non-exempt devices
- Non-premarket Requirements (hospital reprocessors)
  - **August 14, 2001,** registration & listing
  - **August 14, 2002,** rest of non-premarket req.

*****_All other reprocessed class III SUDs may only be available under Investigation Device Exemption (IDE) regulation._



# Examples of SUDs

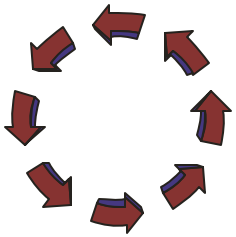
- Surgical saw blades
- Balloon angioplasty (PTCA) catheters
- Laparoscopy scissors
- Endotracheal tubes
- Electrosurgical electrodes and pencils
- Biopsy forceps



# FDA Authority: Federal Food, Drug, & Cosmetic Act as amended (FD&C Act)

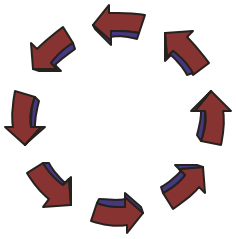
- Medical Device Amendments of 1976 & 1992
- Safe Medical Devices Act of 1990
- Food and Drug Administration Modernization Act of 1997
- Regulations implementing FD&C Act
  - Title 21 Code of Federal Regulations Parts 800-1299

www.fda.gov/cdrh/devadvice/365.html#cfrindexes



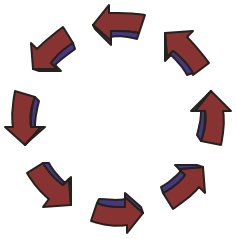
# Regulatory Requirements

- Premarket Requirements
  - Premarket Notification (510(k))
    (21 CFR Part 807)
  - Premarket Approval (PMA)
    (21 CFR Part 814)



# Regulatory Requirements
## *(continued)*

- Non-premarket requirements (Gen. Controls)
  - Registration & Device Listing (21 CFR Part 807)
  - Medical Device Reporting (21 CFR Part 803)
  - Tracking (21 CFR Part 821)
  - Corrections & Removals (21 CFR Part 806)
  - Quality System (QS) Regulation (21 CFR Part 820)
  - Labeling (21 CFR Part 801)

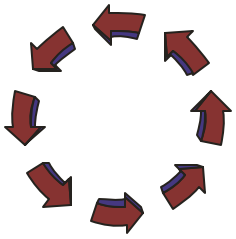


# Classification

Three classes based on risk:

- Class I (least risk): General controls
  - with exemptions
  - without exemptions
- Class II: Special controls
  - with exemptions
  - without exemptions
- Class III (greatest risk): Premarket Approval

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm



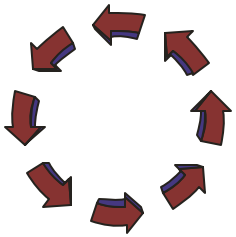
# Types of Premarket Submissions

- Premarket Notification (510(k))

  substantial equivalence (SE) to a legally marketed device

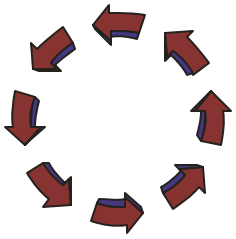
- Premarket Approval (PMA)

  a new device not previously marketed or an existing device seeking a new intended use



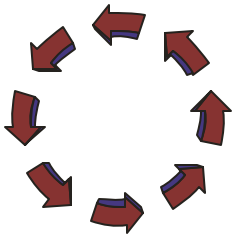
# Premarket Notification 510(k)

- What is it?
  - Section 510(k) of the FD&C Act
  - Marketing clearance submission
  - Application submitted 90 days before marketing (no form)



# Premarket Approval (PMA)

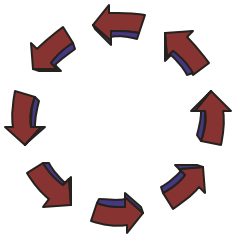
- Class III:  the most stringent regulatory category
  - Devices for which insufficient information exists to assure safety and effectiveness by General or Special Controls
  - Not substantially equivalent through 510(k) process



# SUD Premarket Submission Requirements

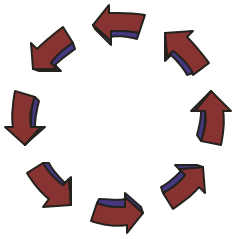
If SUD is a:

- **class I** or **class II exempt** device, **no** premarket submission
- **class I** or **class II non-exempt** device, a **premarket notification** submission (510(k))
- **class III device,** generally a **premarket approval** application (PMA) but few by 510(k)



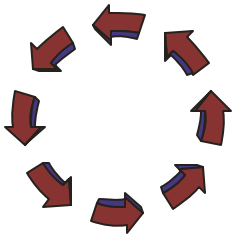
# SUD Premarket Notification (510(k))

- **510(k)** must demonstrate reprocessed SUD is as safe & effective as a legally marketed device for which a PMA is not needed by comparing to
  - original equipment manufacturer (OEM) device, or
  - another reprocessed device that is found substantially equivalent.



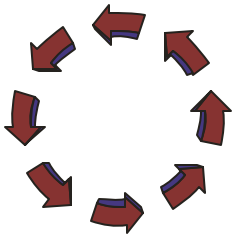
# PMA vs. 510(k)

- PMA
  - Valid scientific evidence
  - Risk/benefit analysis
- 510(k)
  - Substantial equivalence



# Non-premarket Requirements

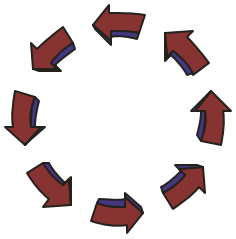
- Registration & Listing
- Medical device reporting (MDR)
- Medical device tracking
- Reports of corrections and removals
- Quality System (QS) regulation
- Labeling



# Registration & Listing
## (21 CFR Part 807)

- Owners and operators of establishments that manufacture devices, including reprocessing of SUDs, must:
  - register their establishments with FDA (FDA Form 2891), and
  - list each reprocessed SUD (FDA Form 2892)

www.fda.gov/cdrh/dsma/rlman.html

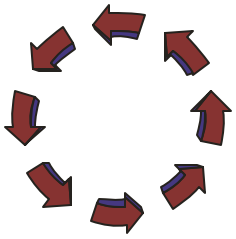


# Manufacturer Reporting Requirements under MDR
## (21 CFR Part 803)

- Report device-related deaths, serious injuries, & malfunctions
- Report within 30 calendar days after becoming aware of event
- Report within 5 working days after becoming aware if event involves a remedial action
- Submit baseline reports and annual updates

*Note: hospital must also report device-related deaths and serious injuries under the **user facility** reporting provisions (shorter time frames)*

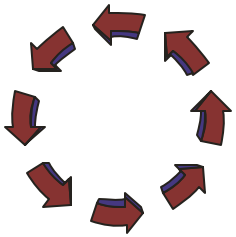
www.fda.gov/cdrh/osb/guidance/1334.html



# Tracking
## (21 CFR Part 821)

- **Purpose**: to promptly locate specific devices in commercial distribution in the event corrective action or notification about the device is necessary
- **Triggered** by a specific FDA tracking order to the manufacturer/reprocessor

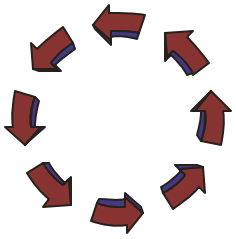
www.fda.gov/cdrh/devadvice/353.html



# Corrections & Removals
## (21 CFR Part 806)

- Must submit within 5 working days a written report to FDA of corrective action or removal of a device that poses a public health risk
  - **Correction -** the repair, modification, adjustment, relabeling, destruction, or inspection of a device ….
  - **Removal -** moving the device to another location for the purpose of repair, modification, adjustment, relabeling, destruction, or inspection ….

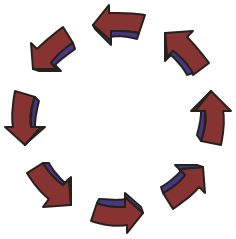
**www.fda.gov/cdrh/devadvice/51.html**



# Quality System
## (21 CFR Part 820)

- Governs the methods used in, and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices
- Process validation

www.fda.gov/cdrh/devadvice/32.html

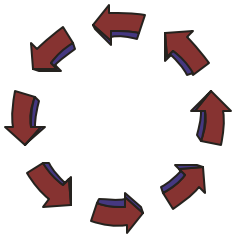


# Labeling
## (21 CFR Part 801)

- General labeling requirements for medical devices

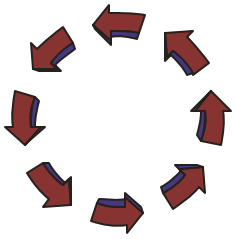
- Not limited to adequate directions for use

www.fda.gov/cdrh/devadvice/33.html



# Where To Go For Help

- Division of Small Manufacturers Assistance (DSMA):
  - Phone (301) 443-6597; (800) 638-2041
  - Facts-On-Demand (800) 899-0381 or (301) 827-0111
  - Device Advice website www.fda.gov/cdrh/devadvice/11.html#start



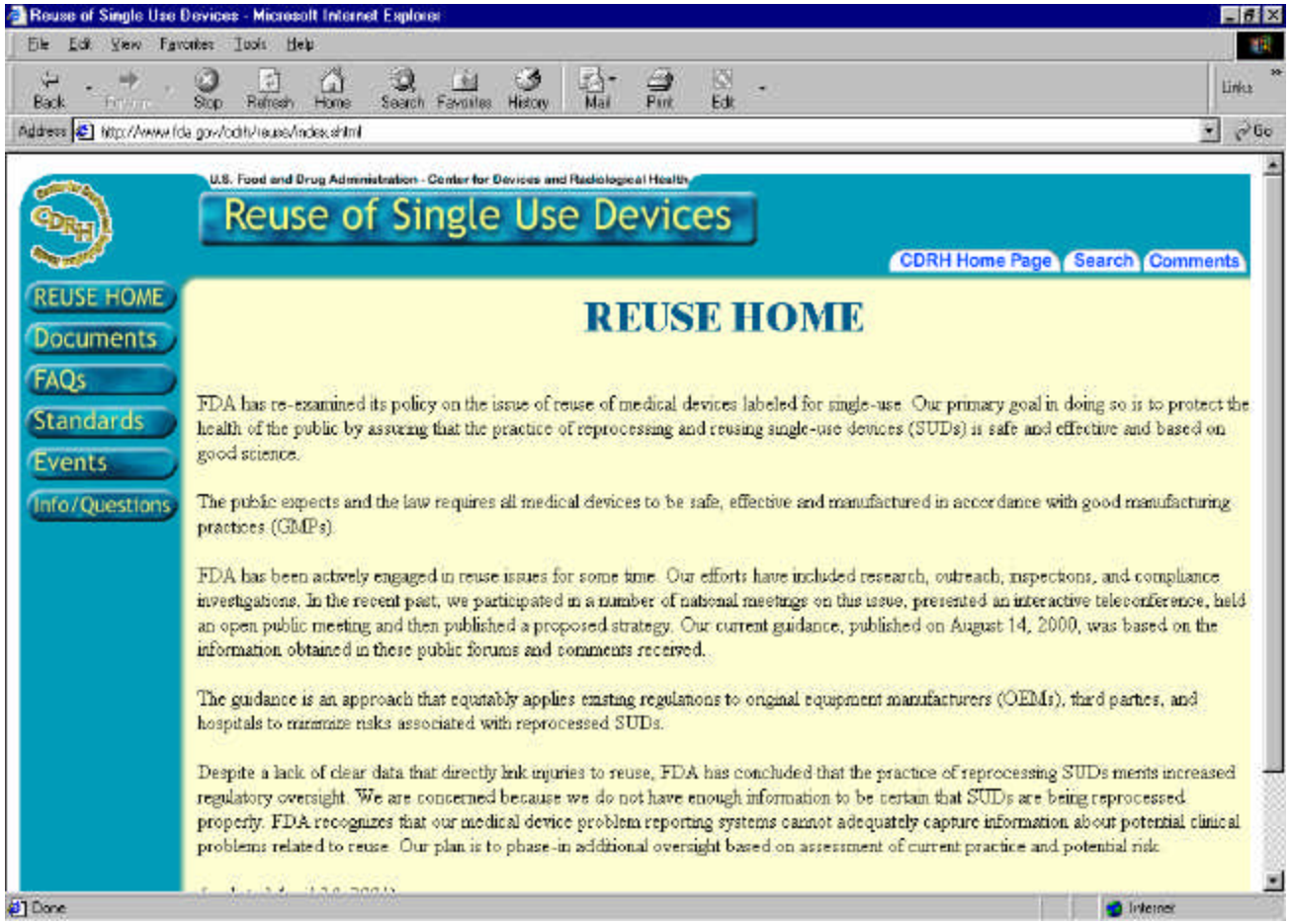
# Where To Go For Help
## *(continued)*

- CDRH website has:
  - Quality System Inspection Technique (QSIT) Handbook
  - Design Control Guidance
  - Medical Device Quality Systems Manual

www.fda.gov/cdrh/dsma/cgmphome.html

www.fda.gov/cdrh/index.html

# Reuse Website




www.fda.gov/cdrh/reuse/index.shtml